Under the Paperwork Reduction Apt of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number.

Substitute for form 1449B/PTO				Complete if Known		
				Application Number	10/574,438	
INF	ORMATION DIS	CLOS	URE	Filing Date 04/03/2006		
STATEMENT BY APPLICANT				First Named Inventor	NADESON, Raymond	
	(11-2-2			Art Unit	1629	
(Use as many sheets as necessary)				Examiner Name	Savitha M. RAO	
Sheet 1 of 3		Attorney Docket Number	DAVI-007/00US 040722-2006			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Cite Initials* No.		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		GARY J. BENNETT et al., "A peripheral mononeuropathy in rat that produces disorders of pain sensation like those seen in man," Pain, 1988, Vol. 33: pgs. 87-107	
		DAVID A. BROWN, et al., "Neural KCNQ (Kv7) channels," British Journal of Pharmacology, 2009, Vol. 156; pgs.1185-1195	
		HUEI-SHENG VINCENT CHEN et al., "The chemical biology of clinically tolerated NMDA receptor antagonists," Journal of Neurochemistry, 2006, Vol. 97: pgs. 1611-1626	
		WAYNE E. CHILDERS JR et al., "N0Methyl-D-Aspartate Antagonists and Neuropathic Pain: The Search for Relief," J. Med. Chem., 2007, Vol. 50: pgs. 2557-2562	
		ANTON J.M. de CRAEN et al., "Analgesic efficacy and safety of paracetamol-codeine combinations versus paracetamol alone: a systematic review," BMJ, 1996, Vol. 313: pgs. 321-325	
		RAYMOND A. DIONNE, "Additive Analgesic Effects of Oxycodone and Ibuprofen in the Oral Surgery Model," J. Oral Maxillofac Surg., 1999, Vol. 57: pgs. 673-678	
		ROBERT H. DWORKIN et al., "Pharmacologic management of neuropathic pain: Evidence-based recommendations," Pain, 2007, Vol. 132: pgs. 237-251	
		BRADLEY S. GALER et al., "Development and preliminary validation of a pain measure specific to neuropathic pain: The Neuropathic Pain Scale," Neurology, 1997, Vol. 48; pgs. 332-338	
		COLIN S. GOODCHILD et al., "Comibation Therapy with Flupirtine and Opioid: Open-Label Case Series in the Treatment of Neuropathic Pain Associated with Cancer," Pain Medicine, 2008, Vol. 9, No. 7: pgs. 939-949	
		VALENTINE K. GRIBKOFF, "The therapeutic potential of neuronal KCNQ channel modulators," Expert Opin. Ther. Targets, 2003, Vol. 7, No. 6: pgs. 737-748	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Apt of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number.

Substitute for form 1449B/PTO				Complete if Known			
				Application Number	10/574,438		
INF	FORMATION DIS	CLOS	URE	Filing Date	04/03/2006		
ST	ATEMENT BY AF	PPLIC	ANT	First Named Inventor	NADESON, Raymond		
	///ee ee			Art Unit	1629		
	(Use as many sheets as nec	essary)		Examiner Name	Savitha M. RAO		
Sheet 2 of 3		Attorney Docket Number	DAVI-007/00US 040722-2006				

		NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹						
		GUIDELINE CENTRAL, "Guideline: Pharmacologic management of neuropathic pain: Evidence-based recommendations," accessed on February 9, 2010, 19 pages, URL: http://www.guidelinecentral.com/CustomContentRetrieve.aspx?ID=1826487&A=Searc					
		P. HLAVICA et al., "Investigation on the Pharmacokinetics and Biotransformations of the Analgesic Flupirtine in Humans," Arzneimittelferschun, 1985, Vol. 35: pgs. 67-74 English Translation					
		REGINA JAKOB et al., "Innuence of flupirtine on a G-protein coupled inwardly rectifying potassoum current in hippocampal neurones," British Journal of Pharmacology, 1997, Vol. 122: pgs. 1333-1338					
		SUN HO KIM et al., "An experimental model for peripheral neuropathy produced by segmental spinal nerve ligation in the rat," Pain, 1992, Vol. 50: pgs. 355-363					
		J. KORNHUBER et al., "Flupirtine shows functional NMDA receptor antagonism by enhancing Mg2+ block via activation of voltage independent potassium channels," J. Neural Transm, 1999, Vol. 106: pgs. 857-867					
		MARIA MARTIRE, et al., "M Channels Containing KCNQ2 Subunits Modeulate Norepinephorine, Aspartate, and GABA Release from Hippocampal Nerve Terminals," The Journal of Neuroscience, January 21, 2004, Vol. 24, No. 3; pgs. 592-597					
		F. GILBERT McMAHON, et al., "Clinical experience with flupirtine in the U.S.," Postgraduate Medical Journal, 1987, Vol. 63: pgs. 81-85					
		FRANCESCO MICELI, et al., "Molecular pharmacology and therapeutic poetential of neuronal Kv7-modulating drugs," Current Opinion in Pharmacology, 2008, Vol. 8; pgs. 65-74					
		GORDON MUNRO, et al., "Kv7 (KCNQ) Channel Modulators and Neuropathic Pain," J. Med. Chem., 2007, Vol. 50; pgs. 2576-2582					
		KIMBALL NILL, "Glossary of Biotechnology Terms," 3 rd Edition, CRC Press, 2002: pg13					

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO**: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Apt of 1995 no Persons are required to respond to a collection of information unless it contains a valid OMR control number.

Substitute for form 1449B/PTO				Complete if Known			
<u> </u>				Application Number	10/574,438		
INF	FORMATION DIS	CLOS	URE	Filing Date	04/03/2006		
ST	ATEMENT BY AF	PPLIC	ANT	First Named Inventor	NADESON, Raymond		
	// las as were sheets as we			Art Unit	1629		
(Use as many sheets as necessary)				Examiner Name	Savitha M. RAO		
Sheet 3 of 3		Attorney Docket Number	DAVI-007/00US 040722-2006				

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		N. N. OSBORNE et al., "Protection of Rabbit Retina From Ischemic Injury by Flupirtine," Investigative Opthalmology & Visual Science, February 1996, Vol. 37, No. 2: pgs. 274-280	
		C. G. PARSONS, et al., "Comparative Patch-clamp Studies with Freshly Dissociated Rat Hippocampal and Sriatal Neurons on the NMDA Receptor Antagonistic Effects of Amantadine and Memantine," European Journal of Neuroscience, 1996, V. 8; pgs. 446-454	
		GAYLE M. PASSMORE, et al., "KCNQ/M Currents in Sensory Neurons: Significance for Pain Therapy," The Journal of Neuroscience, August 6, 2003, Vol. 23, No. 18; pgs. 7227-7236	
		NAVIL F. SETHNA et al., "Analgestic and Cognitive Effects of Intravenous Ketamine-Alfentanil Combinations Versus Either Drug Alone After Intradermal Capsaicin in Normal Subjects," Anesth Analg, 1998, Vol. 86: pgs. 1250-1256	
		MEGUMI SHIMOYAMA et al., "Gabapentin enhances the antinociceptive effects of spinal morphine in the rat tail-flick test," Pain, 1997, Vol. 72: pgs. 375-382	
		HONG-SHENG WANG, et al., "KCNQ2 and KCNQ3 Potassium Channels Subunits: Molecular Correlates of the M-Channel," Science, 1998, Vol. 282; pgs.1890-1893	
		YONG-JIN WU, et al., "(S)-N-[1-(3-Morpholin-4-ylphenyl)ethyl]-3-phenylacrylamide: An Orally Bioavailable KCNQ2 Opener with Significant Activity in a Cortical Spreading Depression Model of Migraine," J. Med. Chem., 2003, Vol. 46; pgs. 3197-3200	
		HEIKE WULFF,et al., "Voltage-gated Potassium Channels as Therapeutic Drug Targets," Nat Reev Drug Discov., December 8, 2008, Vol. 8, No. 12; pgs. 982-1001	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO**: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

